

**EXHIBIT 4**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

LP MATTHEWS, L.L.C.	)	
	)	
Plaintiff,	)	Civil Action No. 04-1507 (SLR)
v.	)	
	)	
BATH & BODY WORKS, INC.; LIMITED	)	
BRANDS, INC.; KAO BRANDS CO.	)	
(f/k/a THE ANDREW JERGENS	)	CONFIDENTIAL
COMPANY); and KAO CORPORATION	)	
	)	
Defendants.	)	
	)	

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**RESPONSIVE EXPERT REPORT OF CHRISTOPHER T. RHODES  
PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 26(A)(2)(b)**

Pursuant to Rule 26(A)(2)(B), Fed. R. Civ. P., and on behalf of Plaintiff L.P. Matthews, L.L.C., I submit the following report responding to the reports of Dr. Robert Y. Lochhead and Mr. John C. Carson. Mr. Carson submitted a report on behalf of defendants Limited Brands, Inc. and Bath & Body Works, Inc., et al. (collectively, "the Limited defendants") and Dr. Lochhead submitted a report on behalf of defendants Kao Corporation and Kao Brands Company (collectively "the Kao defendants"). I reserve the right to supplement or modify these opinions and the bases for them depending on the proofs presented by the defendants or on additional discovery or other information. I am the same Christopher T. Rhodes who provided a February 28, 2006 expert report concerning infringement issues in this case. I incorporate that report. In preparing for this report I have, *inter alia*, examined the expert reports of Dr. Lochhead and Mr. Carson as well as the prosecution file history of the '062 patent. I provide this second report concerning the scientific aspects of the validity issues for the '062 patent.

## SUMMARY OF OPINIONS AND TESTIMONY

### **I. DEFENDANTS' REPORTS**

The arguments presented by Dr. Lochhead and Mr. Carson show a considerable degree of overlap and, thus, in the interest of brevity, I will consider substantial portions of the two reports simultaneously. Since Mr. Carson has personally conducted some experiments which he opines demonstrate serious limitations of the teachings of the '062 patent, I will devote part of this report exclusively to those experiments.

Both Dr. Lochhead and Mr. Carson assert that the '062 patent is invalid since the invention described by the inventors was obvious. It is, of course, often easy with the benefit of hindsight to claim that an invention is obvious. The facts, however, do not support their assertions.

The reports of Dr. Lochhead and Mr. Carson only present two pieces of literature that were not before the patent examiner in allowing the '062 patent: Musher patent (1948) and PDR 1969. Neither the Musher patent nor the PDR 1969 validly supports their claim of obviousness. This data is of very limited relevance to the formulations of the type described in the '062 patent. The Musher patent concerns the use of finely divided, coarse fractions of de-hulled oats in cosmetic products such as skin lotions. It does not refer to the use of orange oil in combination with oat grain derivatives for the purpose of treating unwanted materials on the human skin without damaging the skin. It does not suggest the use of oat grain derivatives to emulsify orange oil in topical products. Indeed, the patent does not specifically refer to emulsifying properties of oats for any purpose. Thus, the patent does not provide any incentive to the skilled artisan to develop the products of the type which are disclosed in the '062 patent. Most notably, neither expert identified a reference that discloses the use of orange oil in such products.

The PDR 1969 reports that oatmeal can provide relief of irritation, but it does not hint at the use of this material in cleaning lotions. Nor does it describe the use of oat products in cleaning lotions containing orange oil.

The information in Musher and PDR 1969 concerning the purported advantage in the use of topical oatmeal was present in data that was considered by the '062 patent examiner. Juliano et al. in the '995 patent state (column 3, line 1), "Addition of this special oat flour, due to its emollient characteristic, aids in relieving skin irritation which may develop while not effecting the foam characteristic of the bath oil." (Emphasis added.) Thus neither Musher nor the PDR 1969 add any new information to that which was considered by the patent office at the time when the patentability of the '062 patent was being considered.

The other references which the experts for the defense have put forward, namely Coleman, Dellutri, Juliano, and Jones, were all considered and applied by the examiner of the '062 patent. Thus any conclusion that the literature clearly demonstrates obviousness of necessity also requires the conclusion that the patent examiner made an erroneous decision when issuance of the patent was granted. The arguments now put forward by the defense experts with respect to the above literature are not novel. The patent file history shows that the distinction between the teachings of the '062 patent and that of the previous literature was fully explored. (See September 18, 1990 Response to Office Action.)

## **II. REFERENCES OF RECORD AND BOARD OPINION**

I now consider four pieces of literature, namely Coleman, Dellutri, Juliano, and Jones, all of which were referred to by the patent examiner in the prosecution file history of the 062 patent. (See May 17, 1990 letter to J. Spear.) To begin with, none of these references cited by Dr. Lochhead or Mr. Carson teaches the use of orange oil to clean human skin or as a cleaning

ingredient in a cleaning composition for use on human skin. Nor do any of these references provide any motivation or suggestion to combine their teachings.

The Coleman paper, "D-limonene as a Degreasing Agent," does not make any reference whatsoever to use of orange oil. Further, although this paper suggests that two of the formulations which are described therein could be used as hand cleaners, the lack of irritation to the skin is not reliably demonstrated. There is an assertion on page 25, "It caused less skin irritation and had a more pleasant odor than the commercially available engine cleaners," but this document does not contain any report of consumer acceptability studies of the type provided by the '062 patent. Therefore, a skilled artisan would doubt whether regular use of the type of d-limonene products described in Coleman would be without skin irritancy problems.

The Dellutri '937 patent claims are focused on d-limonene, not on orange oil. Further, although this patent does make reference to possible use of its d-limonene product as a hand cleaner, the teachings address industrial types of cleaning materials. More importantly, the '937 patent does not report any human use type studies or testing. Instead, the patent speaks to whether the products affect industrial materials: "It had no apparent detrimental effect when tested for two hours at room temperature on numerous materials such as aluminum, anodized aluminum, steel, rubber, fiberglass, glass, acrylics, and urethane paint." (Column 3, line 57 to column 4, line 4.) The fact that the product had no detrimental effect after a two hour exposure on construction materials would not be particularly reassuring to someone skilled in the art of formulation of products designed for application to the human skin for extensive periods of time.

The '995 Juliani patent teaches the use of finely divided oat flour as a component of cosmetic products. This patent does not suggest that oatmeal may have beneficial properties as an emulsifying agent for orange oil in cleaning lotions.

The '487 Jones patent reports on the process of producing a multi-use cleaning agent, from d-limonene, basically harmless to the human skin. (Column 1, line 55.) This patent does not teach the use of orange oil and does not include skin tests of the type disclosed in the '062 patent. Further, the fact that this patent claims that d-limonene is basically harmless to the skin, whereas the '062 patent points out "orange oil by itself is a skin irritant" (column 1, lines 54-55), means that anyone who has detected skin irritancy due to orange oil will have serious doubts about the reliability of the teachings in Jones insofar as they apply to the non-toxic use of d-limonene in products designed for application to human skin.

Having carefully considered the reports prepared by Dr. Lochhead and Mr. Carson and the references discussed above, I must respectfully disagree with both Dr. Lochhead and Mr. Carson. The combination of Dr. Lochhead's and Mr. Carson's references to the use of d-limonene without any testing of skin irritancy would, in fact, point the person skilled in the art away from the formulation of products that use orange oil for the use of cleansing on human skin. None of the art referred to by Dr. Lochhead and Mr. Carson is concerned with orange oil formulations of the type disclosed in the '062 patent.

It should be noted that neither Musher 1948 nor the PDR 1969 (see Section I) add to the literature which was referred to by the patent examiner during the prosecution file history. These references teach the use of specific oat fractions in cosmetic products. Neither reference suggests that oats emulsify (see Claim 6 of the '062 patent). Juliano, as already referred to in this report, had already indicated the use of oats in cosmetic products to relieve skin irritation.

Finally, in his report, Dr. Lochhead refers to the 1997 decision of the Board of Patent Appeals and Interferences concerning patent application 07/786,804. I understand this application is an abandoned continuation-in-part of the original application of '062 patent. The

'804 application appears to me to have much new information as compared to the '062 patent. For example, the '804 application discusses products which are therapeutic in nature (treatment of sunburn, acne, insect repellent). I am informed that the 1997 decision does not alter the legal status of the '062 patent, but I am not an attorney. The three pieces of prior art literature cited in the decision (Coleman, Dellutri, and PDR 1969), have already been discussed in this report. I do not see anything in the decision concerning this prior art which adds anything to the points which I have already considered. Rather, it is my opinion that the literature cited and the prosecution file history indicate that combining such data would not make the teachings of the '062 patent obvious to someone skilled in the art. The '062 patent presents a balance between the cleaning properties of orange oil and using oat products both for emulsifying purposes and the prophylaxis of irritation.

### **III. CARSON EXPERIMENTS**

I now turn to the experimental data which Mr. Carson himself has apparently recently conducted in his lab as part of his preparation for rendering an expert opinion on the case in suit. These studies consist of three groups. D1 and D2 are comparative studies of d-limonene and orange oil as components of one of the examples (XIX) of the '062 are reported. Mr. Carson concludes that some of the orange oil emulsions which he prepared do not form stable emulsions, though "stability" is not fully defined.

Second, in the experiments reported in D3 and D4, Mr. Carson evaluated a number of oat extracts as emulsifiers with respect to d-limonene (D3) and orange oil (D4). He concludes that some oat extracts are not by themselves effective emulsifiers at concentration at less than 10% weight-in-weight.

Third, in experiment D5, Mr. Carson studied the cleaning ability of various concentrations of orange oil and in comparison to the same concentration of d-limonene in an

oatmeal formulation that is apparently taken from Example V (sample V of the '062 patent). Mr. Carson concluded in D5 that, although the test formulations containing either d-limonene or orange oil had some cleaning effect at high concentrations, formulations with lower concentrations were less effective. Also he concluded, "No meaningful differences were seen between the orange oil formulations and the d-limonene formulations in their ability to remove test materials."

#### **A. Scientific Method**

Consideration of several fundamental elements of the scientific method as currently applied demonstrates that Mr. Carson's studies do not meet the standards of reliable scientific data. There are seven elements of the scientific method which I believe are of particular relevance to any consideration of Mr. Carson's report of his experimental studies, namely (1) sufficiency of description of experimental methods, (2) selection of representative samples, (3) replication of test methods and statistical evaluation of data, (4) use, whenever possible, of quantitative, objective measurements of results, (5) if subjective methods have to be used, sufficiency of replicates by independent observers, (6) validation of methods, and (7) reliability of inferences. I now consider each of these elements in turn with respect to Mr. Carson's studies.

##### 1. Sufficiency of Descriptions of Experimental Methods.

It is a canon of scientific literature that the experimental techniques used by an investigator should be reported in such detail that another investigator experienced in the same discipline could, without undue difficulty, understand exactly how the experiment had been conducted so that they could replicate the studies. Mr. Carson's report is deficient in this regard. For example, the reader is not told the list of the procedures used to make the emulsions. I note that in the '062 patent in column 3, line 65, we are told that "the respective components were mixed and blended." This clearly suggests the use of some type of blender or colloid mill. If

Mr. Carson used such equipment, he should have specified exactly what equipment was used and how it was employed. If he did not use such equipment or if the parameters were not appropriate, it is not surprising that he experienced some failures.

2. Selection of Representative Samples.

In designing an experimental protocol that will be sufficient to characterize the attributes of a set of systems, it is important to explain and justify the selection of sample subsets to be tested if it is not deemed possible to evaluate the properties of all such subsets. The '062 patent describes a number of different formulations. In experiments D1 and D2, Mr. Carson has selected systems that are based on "Example XIX (sic)," *i.e.* sample XIX. However, in D5, the test formulations were based on "Example V (sic)," *i.e.* sample V, of the '062 patent. Mr. Carson does not explain the basis for his sample selection. He does not explain why he used sample XIX for one study and sample V for another study. He does not present any data which is supportive of a conclusion that his discriminating sample results in data that is representative of the overall teachings of the patent.

3. Replication of Testing and Statistical Evaluation of Data.

In any scientific study in which it is known that significant variability of test results is possible, it is essential to replicate some of the individual tests in order to define, at least to some extent, the reproducibility of the test procedure. It is normal procedure to validate analytical methods by replication (often six-fold) of some individual test. The data reported by Mr. Carson is entirely silent with respect to replication of any of his data.

4. Use, Whenever Possible, of Quantitative Objective Measurements of Results.

The scientific method requires that, whenever possible, experimental methods should involve objective, quantitative measurements. Much of Mr. Carson's report consists of

subjective evaluation made by just one observer, *i.e.* Mr. Carson. In fact, a number of his experimental procedures could have used objective quantitative methods. For example, in his cleaning studies, a gravimetric method could have been used to measure loss of weight from the test tile or increase in weight of the wash product. Statements such as that involving the rinsing process used in D5, "holding the tile at an angle of 45° and passing the section with the formula to be rinsed through the running tap water—taking a count of one thousand (approximately one (1) second) and then returning at the same speed," do not inspire confidence in the objectivity, reproducibility, or reliability of the experimental procedure. All the laboratories I have worked in, even back in the 1960's, had a stopwatch available.

#### 5. *Independent Observers*

If subjective methodologies have to be used, there should be a sufficient number of independent observers. If visual observation or other subjective, qualitative, analytical methods have to be made of a system being evaluated, then it is important to use more than one independent observer. For example, in the '062 patent (column 3, lines 14-18) the inventors report that they used a test group of ten persons. In 2006, any subjective evaluation of attributes of the '062 patent should have the benefit of a similar approach.

#### 6. *Validation of Methods.*

When, as in the present instance, a scientist is using experimental techniques which are not standard or official, it is incumbent on that scientist to develop and validate the test method and fully define that the method is reliable for the purpose intended. It may well be appropriate to incorporate the use of controls in such tests and the sensitivity of the test method should be fully demonstrated. Mr. Carson has not reported validation of his test methods. Concern may reasonably be expressed about whether his tests have an appropriate level of selectivity. For example, a 24-hour paint sample placed on a rigid tile at an undisclosed temperature is not a

reasonable surrogate for evaluating a skin cleaning lotion, for which the surface is flexible, the temperature is most commonly above 30° C, and the time to elapse before cleaning is likely to be far less than 24 hours.

7. Reliability of Inferences.

In the above six paragraphs, I have indicated some of the many deficiencies in experimental design of the investigations reported by Mr. Carson. Obviously such deficiencies in experimental method cast fundamental doubts on any conclusion which may be drawn from the studies. Additionally, however, some of the conclusions drawn by Mr. Carson are flawed with respect to the reasoning process used. For example, in the conclusion of D3, Mr. Carson states "two of the extracts" tested are not considered to be extracts because they are intentionally chemically modified to produce surfactants. This statement suggests that Mr. Carter excluded intentionally chemically modified materials from the claims of the '062 patent. But the claims refer to oat grain derivatives and do not exclude chemical modification.

8. Conclusion

In addition to having published approximately 250 peer-reviewed scientific papers, I have on many occasions acted as a reviewer for a number of prestigious peer-reviewed journals. Also, for over 20 years I was the editor of the scientific journal *Drug Development and Industrial Pharmacy*. The experimental studies and conclusions presented by Mr. Carson are, in my considered professional opinion, so impaired that they are entirely unreliable. The nature of these studies is that, at best, they are preliminary "quick and dirties." This is a description which was used by my post-doctoral fellowship supervisor in 1965 concerning initial studies of dispersed systems. Clearly, "quick and dirties" are insufficient to prove the points which are now being considered in the case in suit. Mr. Carson's studies do not reach the level needed for reliable scientific conclusions to be obtained.

Finally, it is surprising to me that Mr. Carson feels able to offer expert opinion on legal and scientific matters and also feels comfortable in acting as a fact witness for his own experimental studies. I think it would have been preferable to have clearly separated the fact witness and expert witness functions. This, I believe, is especially important in view of the subjective nature of much of Mr. Carson's studies.

I consider here two of the conclusions reached by Mr. Carson as a result of his experimental: (1) a purported finding that some oat extracts had insufficient emulsifying power at low concentrations, e.g. 5%; and (2) a purported finding that there is no difference in cleaning power between orange oil as compared to comparable products containing d-limonene. As indicated in previous sections of this report, Mr. Carson's experimental studies are so defective that no reliance can be placed on them. If, for the sake of argument, however, we hypothesize that some oat extracts are not sufficient by themselves to produce stable emulsions at low concentrations, this does not mean that a stable emulsion cannot be produced. The '062 patent (column 4, lines 24-26) states, "Applicants tested oatmeal gum and oatmeal to act as the *primary* emulsifier" (emphasis added). Obviously the inventors were aware that in some instances other emulsifiers could be added. Indeed the use of a combination of emulsifiers is common in formulation of emulsions. I understand from counsel, for example, that the word "comprise" as used in Claim 6 and 9 does not exclude the presence of other components and, thus, other emulsifiers could be used in products which would form within the ambit of Claim 1.

#### **IV. d-LIMONENE IS NOT ORANGE OIL**

With respect to Mr. Carson's purported finding that there are no significant differences between the cleaning power of orange oil products and comparable products containing d-limonene, I have already discussed various serious deficiencies in the experimental protocols. In particular, I have indicated that Mr. Carson has not reported validation data for his methods,

incorporated any controls in his cleaning study, or reported any data on selectivity. In order to be meaningful, not only should the cleaning study involve quantitative, objective measurements, it should also demonstrate selectivity. In other words, it should be clearly shown that the study can discriminate between good cleaners, less good cleaners, poor cleaners, *etc.* Mr. Carson's study does not address any of these issues.

I note that from the '062 file history, that Mr. Timothy J. Martin wrote to J. Spear of the patent office on September 18, 1990 and states on pages 2 and 3 of his letter:

Applicants have found that undistilled orange oil has higher cleaning properties when used in a composition than distilled d-limonene. Applicants have tested the compositions produced according to the ranges of the present application wherein an equal weight percent of d-limonene was substituted for the orange oil. In each case, the orange oil based composition had superior cleaning properties than the identical composition with an equivalent amount of d-limonene substituted for the orange oil. While Applicants believe that other esters and volatiles in the orange oil may contribute to the enhanced cleaning properties, although the exact reason for the enhanced cleaning properties has not yet been determined. Nonetheless, Applicants have learned of a surprising result from the raw orange oil in these enhanced cleaning properties. This distinction over the use of d-limonene in the prior art is significant and not at all obvious. Indeed, Applicants have found that their composition is effective on substances such as urethane caulking, paint and tar that resist d-limonene cleaning compositions.

This finding is indeed surprising. However, with the benefit of hindsight, one can see a sound theoretical foundation for this observation. Different organic solvents display somewhat different solubility capacities with respect to different solutes. And also the possibility of synergism in the overall dissolution process between different molecular species does exist. Thus the natural product orange oil, which contains a number of different molecular species, may well be superior as a cleaning material to the single molecular component d-limonene when used by itself.

In conclusion, I am firmly of the opinion that the patent office did not err in issuing the '062 patent. The criticisms advanced by Dr. Lochhead and Mr. Carson are unconvincing and without reliable factual basis. Finally, the office action on the abandoned continuation-in-part application, which was addressed to the use of similar products for OTC (over the counter) pharmaceutical use rather than simply cosmetic use, does not seem to me to have any direct bearing on the validity of the '062 patent, which is clearly directed to a cleansing lotion.

#### **V. DOCUMENTS CONSIDERED**

In forming these opinions, I considered Dr. Lochhead's and Mr. Carson's reports and the references cited herein, the file history of the '062 patent and the file history of U.S. patent application serial no. 07/786,804, and the transcripts of the depositions of Douglas Greenspan, Phillip Low, and Timothy Martin.

#### **VI. SUPPLEMENTATION**

My report represents my present and best opinion regarding the above matters. Should additional information or testimony become available, I reserve the right to revise or supplement my opinions, analysis or conclusions and the bases for them. I understand that I may also be called upon to provide an opinion and expert testimony to rebut opinions or proofs presented by the Limited or Kao defendants.

By:

C T Rhodes  
Christopher T. Rhodes, Ph. D.

On: March 22, 2006

DCI 45681516.6

**CERTIFICATE OF SERVICE**

I hereby certify that on the 31<sup>st</sup> day of March, 2006, the attached **RESPONSIVE EXPERT REPORT OF CHRISTOPHER T. RHODES PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 26(A)(2)(b)** was served upon the below-named counsel of record at the address and in the manner indicated:

Richard L. Horwitz, Esquire  
Potter Anderson & Corroon, LLP  
Hercules Plaza, 6<sup>th</sup> Floor  
1313 North Market Street  
P.O. Box 951  
Wilmington, DE 19899-0951

HAND DELIVERY

Arthur I. Neustadt, Esquire  
Oblon, Spivak, McClelland, Maier & Neustadt, P.C.  
1940 Duke Street  
Alexandria, VA 22314

VIA ELECTRONIC MAIL

Francis G.X. Pileggi, Esquire  
Fox Rothschild LLP  
Suite 1300  
919 North Market Street  
Wilmington, DE 19899

HAND DELIVERY

John Ward, Esquire  
Ward & Olivo  
708 Third Avenue  
New York, NY 10017

VIA ELECTRONIC MAIL



Lauren E. Maguire